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EXAMINER

NGUYEN, TRAN N

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ADVISORY ACTION

Response to Amendment

As per claims 1, 14, the rejection under 35 USC 112, second paragraph regarding “using” and “information” imposed in the previous Office Action is hereby withdrawn in view of Applicant’s amendment to claims 1, 14.

The remainder of the rejection imposed in the previous Office Action is hereby maintained.

Response to Arguments

Applicant's arguments filed 01/26/2008 have been fully considered but they are not persuasive.

As per claim 1, on page 17-18 Applicant argues that “tracking” is not “updating”, and that “tracking” “is clearly defined and supported by paragraph 28 of the specification”.

In response to applicant's argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., a tracking component 66 capable of cross-referencing data with newly acquired data) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In paragraph 28 of the specification Applicant discloses: “server system 12 includes... a tracking component 66 for tracking data... Tracking component 66 tracks and cross-references data, including modifying existing data”.

Based on Applicant’s disclosure, Applicant provides no definition for “tracking”. From Applicant’s disclosure, tracking component 66 performs two distinct functionalities: 1) tracks data, and 2) cross-references data. Based on the grammar of paragraph 28, Examiner interprets “including” to refer to both “tracks” and “cross-references”.

In determining the scope of the claim, Examiner relies on Applicant’s specification which discloses that tracking data comprises modifying existing data. Examiner also relies on Microsoft Computer Dictionary, Fifth Edition which defines “track” as “in data management, to follow the flow of information through a manual or an automated system”.

Based on the specification and the level of ordinary skill in the art, Examiner submits that “tracking” is interpreted, to the extent possible, to be updating data.

Additional clarification is requested.

Applicant’s arguments on page 21-24 merely rehash issues addressed in the previous Office Action, and incorporated herein.

On page 25-26 Applicant argues that paragraph 35 of the specification provides a definition for “template”.

In paragraph 35 of the specification Applicant discloses:

[0035] CRCS 10 is utilized to collect, track, display, and disseminate real time information regarding CS data for a clinical research entity. In one embodiment, CRCS 10 utilizes a plurality of standardized templates for inputting CS data 92 for a clinical study. CRCS 10 also utilizes the plurality of standardized templates to display CS data 92 on client system 14. In one embodiment, each standardized template is in a Java ® format, a C++ computer program format, or a C computer program format. In another embodiment, each standardized template is in an eMatrix ® format (eMatrix is a registered trademark of MatrixOne, Inc. Chelmsford, Massachusetts). Each standardized template contains fields that prompt a user to enter specific CS data 92 or displays specific CS data 92 for a user to view and analyze. These fields may also capture and display workflow for a specific clinical study.

Examiner submits that paragraph 35 does not provide a definition for “a user selected template” as recited in claim 1. Instead, only alternative embodiments and optional, non-committal features are disclosed.

On page 26 Applicant argues “Brown does not teach or suggest that a *protocol* is developed as a result of clinical information entered through a *template* or that a “protocol” allows user entry of CS data via a set of fields or the display of such data” (emphasis in original).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., developing a protocol as a result of clinical information entered through a template, allowing user entry of CS data via a set of fields, displaying CS data) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

On page 26 Applicant asserts the advantage of “ensur[ing] uniformity amongst all the data collected in a particular study by using the same template throughout the course of a study”.

On page 23 Applicant admits the following:

Still further, Brown discloses that as part of the patient self-assessment, the protocol may present narrowly structured questions as well as suggested answers, and that in the event of ambiguous or incomprehensible answers, the testing protocol may include formulating additional questions in order to more effectively direct the patient’s response towards a more objectively analyzable answer. *See id.* col. 4, lines 12-19. Additionally, the testing protocol may also include providing a restricted set of possible answers (e.g., multiple choice, true/false). *See id.* These features are designed reduce or eliminate “fuzzy” answers.

Examiner submits that based on the teachings of Brown, as admitted by Applicant, Brown’s protocol includes provisions to extract information from a patient to reduce or eliminate ambiguous and fuzzy answers. Therefore, Applicant's asserted advantage does not distinguish over the applied art.

On page 26 Applicant further argues that “the protocol [of Brown] is changing throughout the course of the study”.

Brown teaches that the medical research expert can either leave the protocol unchanged or modify it as necessary (column 7 line 1-5, Figure 2b label 216).

Based on the evidence presented above, Examiner submits that the protocol of Brown may be constant.

Applicant's arguments on page 26-30 merely rehash issues addressed in the previous Office Action, and incorporated herein.

On page 31 Applicant asserts the features of "aiding clinical research entities, which may engage in numerous different clinical studies simultaneously, to better maintain CS data... improve viewing, analysis, and management of the CS data".

Brown teaches a system capable of collecting research data from a plurality of research subject for analysis (column 2 line 25 to column 4 line 40). Therefore, Applicant's asserted advantage does not distinguish over the applied art.

On page 34 Applicant traverses the Official Notice previously taken.

MPEP 2144.03(C) reads as follows: "**To adequately traverse such a finding [of official notice], an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art.**" See 37 CFR 1.111(b). See also Chevenard, 139 F.2d at 713, 60 USPQ at 241 ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be

inadequate... **If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art** because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate" (emphasis added).

Applicant's traversal in the response filed 09/21/2007 and 01/26/2008 appears to be inadequate because Applicant does not specifically point out the supposed errors, nor did Applicant state why the noticed fact is not considered to be common knowledge or well-known in the art.

Assuming *arguendo* that Applicant's traversal was adequate, Examiner submits class 707 containing therein thousands of references directed towards database query processing.

Brown further teaches a database server (Figure 1 label 130, 132). Brown further teaches data stored in the database for review (column 7 line 27-29).

Based on the evidence presented above, Examiner submits that processing a database query within the embodiment of Brown is predictable and is fully within the grasp of one of ordinary skill in the art.

/T. N./
Examiner, Art Unit 3626

/Joseph Thomas/
Supervisory Patent Examiner, Art Unit 3626